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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/490,291 01/20/00 MELLO

C NA-1151

EXAMINER

HM22/0907

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AMCCP-IP William Medsger
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ART UNIT

PAPER NUMBER

1653

DATE MAILED:

09/07/01

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

FILE COPY

Application No.

9,490,291

Applicant(s)

MELLO ET AL.

Examiner

Holly Schnizer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-16 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 9.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Status of the Claims

1. The Response and Amendment filed June 13, 2001 (Paper No. 11) has been entered. Claim 17 has been cancelled. Therefore, Claims 1-16 and 18 are pending and have been considered on the merits in this Office Action.

Rejections Withdrawn

2. The rejection of Claims 1 and 9 under 35 U.S.C. 112, second paragraph as indefinite as to the term "treating" is withdrawn in light of the amendment to the claims defining the term.

3. The rejection of Claim 2 under 35 U.S.C. 112, second paragraph as indefinite has been withdrawn in light of the amendment to the claim.

4. The rejection of Claim 8 under 35 U.S.C. 112, second paragraph is withdrawn in light of the amendment to the claims.

Rejections Maintained

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7, 8, 12, and 13 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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3. Claims 7, 8, 12, and 13 are again rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP 2172.01. The omitted steps are: the ones associated with "manipulating" the solution, necessary to produce the insoluble fibers.

4. Applicants have amended the claims in an attempt to overcome the previous rejection. Amendment of Claims 7, 8, 12, and 13, as has been done in Claim 16 (which includes the step of forcing the concentrated solution through a spinneret), would overcome this rejection. What is missing in the presently rejected claims is the step that is required to produce the insoluble fibers.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-9, 11-14, 16, and 18 are again rejected under 35 U.S.C. 102(b) as being anticipated by Lombari et al.

3. The previous rejection stated: The Lombari et al. reference teaches a method of purifying and producing concentrated amounts of recombinant and non-recombinant spider silk proteins by solubilization, a host bacterial cell containing the polypeptide and use of organic acids including propionic acids for recovery of concentrated protein. (See Col. 2, line 10-Col. 5, line 47).

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4. Applicant's argument that Lombari et al. teach solubilizing and not purifying has been considered but is not deemed to be persuasive. The claimed method recites identical steps to those of the method of Lombari et al. (see Col. 3, lines 29-46). The claimed method does not recite that the polypeptides recovered in the method are "purified". Thus, the claimed method encompasses methods of solubilization and is patentably indistinguishable over the prior art.

5. In response to applicant's argument that the method of Lombari et al. includes affinity chromatography which is different from the present invention, it is noted that the present claims are not limited to a method which does not involve affinity chromatography.

6. Applicant's argument that the 50%-50% organic acid/HCl used in the Lombari et al. method is not an organic acid has been considered but is not deemed persuasive because propionic acid is an organic acid and Applicants have not submitted any evidence that the addition of other acids (i.e. HCl) would materially change the characteristics of the applicant's invention. "The transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s) of the claimed invention' (In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)" (MPEP 2111.03). "[A]bsent a clear indication in the specification of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising'" (MPEP 2111.03). "When an applicant contends that additional steps or materials in the prior art are excluded by

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the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention" (MPEP 2111.03).

7. In response to applicant's argument that the intended use of the method of Lombari et al. is different from the method of the present invention, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

New Rejections

Claim Rejections - 35 USC § 112

1. Claims 1-16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. Claims 1-16 and 18 are indefinite as to the identity of the "recovered solution" of line 8 (of Claim 1) and its relationship to the solution containing the recovered polypeptides of line 5 (claim 1). Clarification of the claims is required such that it is clear as to what endpoint or goal the method achieves.

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3. Claims 5 and 6 fail to further limit Claim 1 from which they depend since Claim 1 contains the transitional phrase "consisting essentially of" and Claims 5 and 6 contain the broader transitional phrase "comprising". Correction is required.

4. Claims 9-16 are unclear as to where the "insoluble material" of part c (in Claim 9 for example) comes from since the claims recite that "treating" in part b includes the step of "clarifying". In addition, the placement of what is encompassed by the term "treating" at the end of the claim rather than in the step wherein it occurs (step b) is confusing. Claims 10-13 and 15-16 are rejected because they depend from indefinite claims 9 and 14.

5. Claim 18 is rejected because it depends from cancelled Claim 17. Correction of its dependency is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7, 12, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of Claims 1, 9, and 14 further comprising the steps of purifying the solution, concentrating the purified solution, and forcing the concentrated solution through a spinneret wherein said steps are performed under conditions wherein **insoluble fibers of polypeptides** are produced, does not reasonably provide enablement for the methods of Claims 1, 9, and 14 further comprising the step of manipulating said solution under conditions that **insoluble fibers**

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are produced, said manipulating comprising purifying the solution and concentrating the purified solution. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

8. In the present case, the specification does not teach a method wherein insoluble fibers other than insoluble fibers of polypeptides are produced. Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F2d, 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). These factors include (1) quantity of experimentation, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

9. The claims recite a method of isolating a structural protein wherein any insoluble fiber is formed. This encompasses any compound that would form an insoluble fiber. However, the specification only teaches a method wherein an insoluble fiber of a spider silk protein is formed. The specification does not provide guidance as to any other substances which can form insoluble fibers in the claimed method. Without such guidance, one skilled in the art could not predict which substances could be used in the claimed method to form insoluble fibers and accordingly, one skilled in the art would be required to perform undue experimentation to identify other compounds that would form such fibers when using the claimed method. Therefore, one skilled in the art could not make the invention without undue experimentation.

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Conclusions

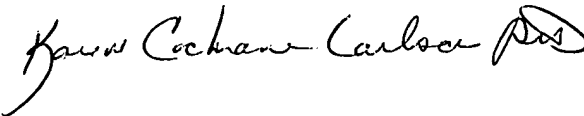
10. No claims are allowable. However, the methods of Claims 2, 10, and 15 appear to be free of the prior art. A thorough search of the sequence databases does not reveal any teaching or suggestion of the claimed methods wherein the polypeptide used in the method is selected from the sequences claimed in Claims 2, 10, and 15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached on Mon. & Thurs., 8am-5:30pm and Tues. & Wed. 9am-2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Holly Schnizer
September 5, 2001


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER